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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|-------------|----------------------|---------------------|------------------|
| 10/049,992 | 10/07/2002 | Andre Beaulieu | BEAU 4 US | 2610 |
| 23566 | 7590 | 06/07/2004 | EXAMINER | |
| OSTRAGER CHONG & FLAHERTY LLP | | | KIM, VICKIE Y | |
| 825 THIRD AVE | | | ART UNIT | |
| 30TH FLOOR | | | PAPER NUMBER | |
| NEW YORK, NY 10022-7519 | | | 1614 | |

DATE MAILED: 06/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,992

Applicant(s)

BEAULIEU ET AL.

Examiner

Vickie Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 October 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for Domestic priority documents under 35 U.S.C. 119(e) and 120.

Information Disclosure Statement

2. The PCT search report has been filed Feb. 19, 2002. However, it fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file but the information referred to therein has not been considered. Submission of PTO-1449 is requested.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-9, 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Reich (US 4,973,466).

The claims are drawn to a solid dressing composition comprising an effective amount(0.5-1%) of fibronectin.

Reich(US'466, hereafter) teaches a solid, wound healing dressing comprising a gel or a solution of fibronectin(0.5-50%) isolated from plasma, a biologically active fragment and analogs thereof. It is noted that the analogs of fibronectin include analogs

Art Unit: 1614

produced by genetic engineering techniques, see column 4, lines 10022 and claims 1, 8-12. US'466 further teaches an inclusion of other beneficial additives such as collagens, vitronectin, laminin, fibrinogen, etc, see col. 4, lines 60-63 and claim 14.

As to the claims 9, 15-19, US'466 teaches collagen(see claim 14 and col. 3, lines 3-52) and other proteins(e.g. albumin) used to produce the flocculent included in the dressing which is used to form crosslinked gel material and provide a matrix for cell growth and migration and for the deposition of wound-healing substances. US'466 also teaches the wound-healing dressings can be employed as delivery systems for medicaments. Although the patent does not explicitly mention about fibrous material, it is well known that collagen and other proteins(e.g. albumin) is well known as fibrous material and thus, the limitation is inherently met by the cited reference(see Pto-892 for evidentiary documents).

Thus, all the critical elements required by the instant claims are well taught and the claims are met by the cited reference.

Claim Rejections - 35 USC § 102/103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1- 24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Beaulieu (US 5641483).

US'483 teaches a topical gel formulation containing an effective amount(0.005-0.5%, see column 3, line 66) of fibronectin, wherein the formulation is used to coat fibers of an absorbent gauze dressing to form a wound healing bandage, see abstract and column 5, lines 50-60. US'483 also teaches a preferred formulation of the patented invention containing fibronectin and other proteins such as laminin, vitronectin and fibrinogen, see column 2, lines 41-44.

As to the claims 10-14, US'483 teaches cellulose derivatives such as sodium carboxymethylcellulose or hydroxypropylcellulose, see example 4 and column 9, lines 10-15. Furthermore, US'483 teaches semi-solid dosage form(i.e. lipogel) containing fibronectin, see column 10, lines 63-67. The limitations recited in the claims 13-14 are considered to be inherent features which is possessed and occurred naturally when the said composition is administered. And thus, the claims are properly included in this claims.

As to the claims 20-24, all the claims are properly included in this rejection since the composition as claimed are taught by the cited reference, the method of making such composition must be embraced as well by the scope of the patent.

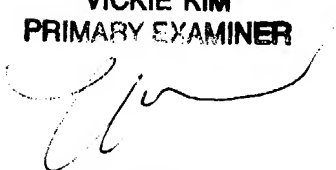
Or Alternatively, the teaching of US'483 would have rendered the instant claims obvious even if the claims may not be anticipated by US'483, because it is well within the level of ordinary skill in the art to make such modification including the differences, if there have, to enhance the overall quality. It is routine pharmaceutical practice to incorporate various techniques and skills available in the art to extend the dosage

forms to improve patients satisfaction and preference which is critical for better compliance and for optimal therapeutic efficacy.

Conclusion

7. No claim is allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579(fax: 571-273-0579). The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

VICKIE KIM
PRIMARY EXAMINER



Vickie Kim
June 1, 2004
Art unit 1614